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NOTICE OF ALLOWANCE AND FEE(S) DUE

210

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05/15/2009

MERCK AND CO., INC P O BOX 2000 RAHWAY, NJ 07065-0907 EXAMINER

WILSON, MICHAEL C

ART UNIT PAPER NUMBER

1632 DATE MAILED: 05/15/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,963	10/07/2003	Piotr Bobrowicz	GFI-108	6071

TITLE OF INVENTION: N-ACETYLGLUCOSAMINYLTRANSFERASE III EXPRESSION IN LOWER EUKARYOTES

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$755	\$300	\$0	\$1055	08/17/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

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If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

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III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

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Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE

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maintenance fee notifications. Note: A certificate of mailing can only be used for domestic mailings of the CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address) Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission. 210 7590 05/15/2009 Certificate of Mailing or Transmission MERCK AND CO., INC I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below. POBOX 2000 RAHWAY, NJ 07065-0907 (Depositor's name (Signature (Date APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 10/680.963 10/07/2003 Piotr Bobrowicz GFI-108 6071 TITLE OF INVENTION: N-ACETYLGLUCOSAMINYLTRANSFERASE III EXPRESSION IN LOWER EUKARYOTES APPLN. TYPE SMALL ENTITY ISSUE FEE DUE PUBLICATION FEE DUE PREV. PAID ISSUE FEE TOTAL FEE(S) DUE DATE DUE nonprovisional YES \$755 \$300 \$0 \$1055 08/17/2009 **EXAMINER** ART UNIT CLASS-SUBCLASS WILSON, MICHAEL C 1632 435-069100 1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). 2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. or agents OR, alternatively, (2) the name of a single firm (having as a member a ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required. registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type) PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment. (A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY) 4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above) 4a. The following fee(s) are submitted: lssue Fee A check is enclosed. Publication Fee (No small entity discount permitted) Payment by credit card. Form PTO-2038 is attached. The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number ______ (enclose an extra copy of this fo Advance Order - # of Copies _ (enclose an extra copy of this form). 5. Change in Entity Status (from status indicated above) a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ■ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2). NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office. Authorized Signature Date Typed or printed name Registration No. This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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10/680,963	10/07/2003	Piotr Bobrowicz	GFI-108	6071
210 7.	590 05/15/2009		EXAMINER	
MERCK AND CO., INC			WILSON, MICHAEL C	
P O BOX 2000			ART UNIT	PAPER NUMBER
RAHWAY, NJ 07	065-0907		1632	
			DATE MAILED: 05/15/200	9

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 423 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 423 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

	Application No.	Applicant(s)	
	10/680,963	BOBROWICZ ET AL.	
Notice of Allowability	Examiner	Art Unit	
	Michael C. Wilson	1632	
	Wilchael C. Wilson	1632	
The MAILING DATE of this communication app All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85 NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT F of the Office or upon petition by the applicant. See 37 CFR 1.31	S (OR REMAINS) CLOSED in b) or other appropriate common RIGHTS. This application is s	n this application. If not included unication will be mailed in due course. THIS	tive
1. \square This communication is responsive to <u>9-16-08</u> .			
2. The allowed claim(s) is/are 76-86 and 88-99.			
 3. ☐ Acknowledgment is made of a claim for foreign priority of a) ☐ All b) ☐ Some* c) ☐ None of the: 1. ☐ Certified copies of the priority documents have 2. ☐ Certified copies of the priority documents have 3. ☐ Copies of the certified copies of the priority documents. 	re been received. re been received in Applicatio	on No	
International Bureau (PCT Rule 17.2(a)).	ocuments have been receive	d in this haddhar stage application from the	
* Certified copies not received:			
Applicant has THREE MONTHS FROM THE "MAILING DATE noted below. Failure to timely comply will result in ABANDON! THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.		e a reply complying with the requirements	
4. A SUBSTITUTE OATH OR DECLARATION must be subr INFORMAL PATENT APPLICATION (PTO-152) which give			
5. CORRECTED DRAWINGS (as "replacement sheets") mu	ıst be submitted.		
(a) \square including changes required by the Notice of Draftsper	rson's Patent Drawing Review	w (PTO-948) attached	
1) 🔲 hereto or 2) 🔲 to Paper No./Mail Date			
(b) ☐ including changes required by the attached Examiner Paper No./Mail Date	's Amendment / Comment o	r in the Office action of	
Identifying indicia such as the application number (see 37 CFR each sheet. Replacement sheet(s) should be labeled as such in			
6. DEPOSIT OF and/or INFORMATION about the deposit attached Examiner's comment regarding REQUIREMENT			
Attachment(s) 1. ☐ Notice of References Cited (PTO-892)	5. ☐ Notice of In	formal Patent Application	
2. Notice of Draftperson's Patent Drawing Review (PTO-948)		ummary (PTO-413),	
3. ☑ Information Disclosure Statements (PTO/SB/08),	Paper No. 7. ⊠ Examiner's	/Mail Date Amendment/Comment	
Paper No./Mail Date 12-11-08 4. ☐ Examiner's Comment Regarding Requirement for Deposit		Statement of Reasons for Allowance	
of Biological Material	o. ☐ Examiner's		
/Michael C. Wilson/			
Primary Examiner, Art Unit 1632			

Art Unit: 1632

EXAMINER'S AMENDMENT

The examiner in this application has changed. Please direct all correspondences to Examiner Michael C. Wilson, Art Unit 1632.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with John David Reilly on 5-5-09.

The application has been amended as follows:

Claims 1-75 and 87 have been canceled.

Claims 76-86 and 88-99 have been allowed.

The claims have been amended as follows:

- 76. A yeast host cell that has been genetically engineered to be diminished or depleted in the activity of an initiating α-1,6-mannosylatransferase and to comprise a nucleic acid sequence encoding an α-1,2-mannosidase, a nucleic acid sequence encoding a N-acetylglucosaminyltransferase I (GnT I), and a nucleic acid sequence encoding an N-acetylglucosaminyltransferase III (GnT III).
- 77. The yeast host cell of claim 76, wherein the GnT III has intracellular catalytic activity.

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78. The yeast host cell of claim 76, further comprising a nucleic acid sequence encoding mannosidase II.

- 79. The yeast host cell of claim 76, wherein the GnT III produces a bisected glycan.
- 81. A yeast host cell that has been genetically engineered to be diminished or depleted in the activity of an initiating α-1,6-mannosylatransferase and to comprise a nucleic acid sequence encoding an α-1,2-mannosidase, a nucleic acid sequence encoding an N-acetylglucosaminyltransferase I (GnT I), a nucleic acid sequence encoding an N-acetylglucosaminyltransferase II (GnT II), and a nucleic acid sequence encoding an N-acetylglucosaminyltransferase III (GnT III).
- 82. The yeast host cell of claim 81, wherein the GnT II and the GnT III have intracellular catalytic activity.
- 83. The yeast host cell of claim 81, further comprising a nucleic acid sequence encoding mannosidase II.
- 84. The yeast host cell of claim 81, wherein the GnT III produces a bisected glycan.
- 86. A yeast host cell that has been genetically engineered to be diminished or depleted in the activity of an initiating α-1,6-mannosylatransferase and to comprise a nucleic acid sequence encoding an α-1,2-mannosidase, a nucleic acid sequence encoding a N-acetylglucosaminyltransferase I (GnT I), a nucleic acid sequence encoding an N-acetylglucosaminyltransferase III (GnT III), and a nucleic acid sequence encoding a mannosidase II.

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88. The yeast host cell of claim 76, wherein the initiating α -1,6-mannosylatransferase is OCH1.

- 89. The yeast host cell of claim 81, wherein the initiating α -1,6-mannosylatransferase is OCH1.
- 90. The yeast host cell of claim 86, wherein the initiating α -1,6-mannosylatransferase is OCH1.
- 91. The yeast host cell of claim 76, wherein the yeast is further diminished or depleted in the activity of Dol-P-Man:Man5GlcNAc2-PP-Dol mannosyltransferase.
- 92. The yeast host cell of claim 81, wherein the yeast is further diminished or depleted in the activity of Dol-P-Man:Man5GlcNAc2-PP-Dol mannosyltransferase.
- 93. The yeast host cell of claim 86, wherein the yeast is further diminished or depleted in the activity of Dol-P-Man:Man5GlcNAc2-PP-Dol mannosyltransferase.
- 94. The yeast host cell of claim 76, further comprising a nucleic acid sequence encoding a UDP N-acetylglucosaminyltransferase (GlcNAc) transporter.
- 95. The yeast host cell of claim 81, further comprising a nucleic acid sequence encoding a UDP N-acetylglucosaminyltransferase (GlcNAc) transporter.
- 96. The yeast host cell of claim 86, further comprising a nucleic acid sequence encoding a UDP N-acetylglucosaminyltransferase (GlcNAc) transporter.
 - 97. The yeast host cell of claim 76, wherein the yeast is methylotrophic.
 - 98. The yeast host cell of claim 81, wherein the yeast is methylotrophic.
 - 99. The yeast host cell of claim 86, wherein the yeast is methylotrophic.

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Support for claims 88-90 is found on pg 10, line 17.

Support for claims 91-93 is found on pg 49, line 7-8.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday, Tuesday, Thursday and Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517.

The official fax number for this Group is (571) 273-8300.

Michael C. Wilson

/Michael C. Wilson/ Patent Examiner